

National Puerto Rican Coalition, Inc. Statement Before the Nonprescription Drug  
Advisory Committee and the Pulmonary-Allergy Drugs Advisory Committee  
U. S. Food & Drug Administration

Presented by Manuel Mirabal, President & CEO  
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On behalf of the National Puerto Rican Coalition (NPRC), representing the interests of eight million Puerto Rican U.S. citizens throughout the country, I am writing to comment on the essentiality of asthma inhalants using CFC's. We believe that the effect that the OTC inhalants have on the environment is very minor compared to their value to people suffering from asthma.

Puerto Ricans living in the United States mainland and in Puerto Rico disproportionately suffers from asthma. Of all the age groups, children are the most affected by asthma, and of all Latino subgroups Puerto Ricans have the highest rate of asthmatics.<sup>1</sup> The American Lung Association (ALA) reports that two thirds of the estimated half a million Latino children showing asthma symptoms are Puerto Rican. Asthma has been estimated to affect as many as 20.1 percent of mainland Puerto Rican children 6 months to 11 years of age. Puerto Ricans had the highest annual asthma mortality rate (40.9).<sup>2</sup> Puerto Rican children have the highest prevalence of active asthma (11 percent) of any group of US children, significantly surpassing African Americans (6 percent) and Whites (3 percent).<sup>3</sup> In Puerto Rico, asthma in children stands at an alarming 32.3 percent.

Puerto Rican and Hispanics already have limited access to health insurance and prescription drugs largely due to their employment in job sectors where insurance is not offered and high poverty rates. Currently, Latinos are the largest ethnic group in the U.S. with the greatest proportion of uninsured. According to an August 2004 Census report, the uninsured rate for Latinos is close to 33 percent, as compared with Blacks at 19.5 percent or non-Hispanic Whites at 11.1 percent. Therefore, it is essential that low cost generic drugs remain available.

NPRC is concerned that if restrictions are placed upon the usage of bronchodilator inhalants it could have a negative impact on our community. Should Primatene and the various store brand bronchodilator inhalants be removed from the market, we anticipate serious public health implications will occur, especially among Hispanics who cannot afford to purchase more expensive medicines.

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1. Centers for Disease Control, Media Relations Fact Sheet, April 2004.  
Lara, Morgenstern, Duan, Brrock. Elevated Asthma Morbidity in Puerto Rican Children: A Review of Possible Risk and Prognostic Factors. Western Journal of Medicine. February 1999.  
2. Ibid.  
3. Carter-Pokras, Gergen. Reported Asthma Among Puerto Rican, Mexican-American, and Cuban Children, 1982 through 1984. American Journal of Public Health, 83.

The potential removal of the product is not a safety issue. Epinephrine is deemed by FDA as safe and effective and has a long history of use in acute asthma. This is an issue of maintaining access to medication that may be required by a patient at a moment's notice.

NPRC believes that there are no OTC alternatives, since these products support medically underserved populations and since they serve an important "rescue" role that the exemption ought to be extended. Due to the public health need for asthma medicines available to those without access to a medical professional for monitoring their asthma at the time of an attack, we urge the FDA to grant OTC epinephrine an essential use designation and continue to make it available to the public until a reformulated OTC product is available.

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